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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/856,372	11/02/2001	Sojiro Shiokawa	Q64460	8305

7590 09/13/2004

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2100 Pennsylvania Avenue N W Suite 800  
Washington, DC 20037-3213

EXAMINER

COLEMAN, BRENDA LIBBY

ART UNIT	PAPER NUMBER
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1624

DATE MAILED: 09/13/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	09/856,372	SHIOKAWA ET AL.	
	<b>Examiner</b>	<b>Art Unit</b>	
	Brenda Coleman	1624	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 01 July 2004.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1 and 18-23 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1 and 18-23 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |   |   |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                        | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)    | Paper No(s)/Mail Date. _____  |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____   | 6) <input type="checkbox"/> Other: _____                                    |

### **DETAILED ACTION**

Claims 1 and 18-23 are pending in the application.

This action is in response to applicants' amendment dated July 1, 2004. Claims 18, 19 and 23 have been amended and claim 24 has been canceled.

### ***Response to Amendment***

Applicants' arguments filed July 1, 2004 have been fully considered with the following effect:

1. With regards to the 35 U.S.C. § 103, obviousness rejection of claims 1 and 18-24 over SATO et al., Journal of Medicinal Chemistry of the last office action, the applicant's arguments have been fully considered but are not found persuasive. The applicant's stated that the compound of claim 1 is unexpectedly superior over the prior art. The applicants pointed to the Test Examples 2 and 4 at pages 37-38 and 39-40, respectively, and in particular, to the tables at pages 38 and 40 of the specification. However, the significance of the data in the showing is not seen.

Claims 1 and 18-23 are rejected under 35 U.S.C. 103(a) as being unpatentable over SATO et al., Journal of Medicinal Chemistry, for reasons of record and stated above.

2. With regards to the 35 U.S.C. § 103, obviousness rejection of claims 1 and 18-24 over SATO et al., EP 0 806 419 of the last office action, the applicant's arguments have been fully considered but are not found persuasive. The applicant's stated that they respectfully traverse this rejection for very similar reasons to those discussed above with respect to Sato. That is that the compound of claim 1 is unexpectedly superior

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over the prior art. The applicants pointed to the Test Examples 2 and 4 at pages 37-38 and 39-40, respectively, and in particular, to the tables at pages 38 and 40 of the specification. However, the significance of the data in the showing is not seen.

Claims 1 and 18-23 are rejected under 35 U.S.C. 103(a) as being unpatentable over SATO et al., EP 0 806 419, for reasons of record and stated above.

3. The applicant's amendments and arguments are sufficient to overcome the 35 U.S.C. § 112, second paragraph rejections labeled a), b), c) and h) of the last office action, which are hereby **withdrawn**. However, with regards to the 35 U.S.C. § 112, second paragraph rejections labeled d), e), f) and g) the applicant's amendments and remarks have been fully considered but they are not persuasive.

d) The applicants' stated that claim 21 is directed to a serotonin 5-HT<sub>3</sub> receptor antagonistic agent which is a "compound" that contains a statement of intended use of the compounds of which is not given any patentable weight.

e) The applicants' stated that claim 21 is directed to a serotonin 5-HT<sub>3</sub> receptor antagonistic agent which is defined as a "compound".

f) The applicants' stated that claim 22 is directed to a serotonin 5-HT<sub>3</sub> receptor partial activator which is a "compound" that contains a statement of intended use of the compounds of which is not given any patentable weight.

g) The applicants' stated that claim 23 is directed to a antiemetic agent which is defined as a "compound".

Claim 21-23 rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention, for reasons of record and stated above.

4. With regards to the obviousness-type double patenting rejection of claims 1 and 18-24 over U.S. Patent No. 6,037,342 of the last office action, the applicant's arguments have been fully considered but are not found persuasive. The applicant's stated that Claims 1 and 18-24 are not an obviousness-type double patenting of Claims 1-4 of U.S. '342 for the same reasons that EP '419 fails to render obvious Claims 1 and 18-24. However, the compound of claim 1 is within the scope of the compounds claimed and which patent protection was granted in U.S. 6,037,342.

Claims 1 and 18-23 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-4 of U.S. Patent No. 6,037,342, for reasons of record and stated above.

5. With regards to the provisional obviousness-type double patenting rejection of claims 1 and 18-24 over copending Application No. 10/219,496 of the last office action, the applicant's arguments have been fully considered but are not found persuasive. The applicant's stated that Claims 1 and 18-24 are not an obviousness-type double patenting of Claim 3 of copending Application No. 10/219,496 for the same reasons that EP '419 fails to render obvious Claims 1 and 18-24. However, the compound of claim 1 is within the scope of the compounds claimed and which patent protection is being sought.

Claims 1 and 18-23 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 3 of copending Application No, 10/219,496, for reasons of record and stated above.

6. The applicant's amendments and arguments are sufficient to overcome the objection of claim 19 labeled paragraph 9) of the last office action, which is hereby **withdrawn**.

In view of the amendment dated July 1, 2004, the following new grounds of rejection apply:

### ***Double Patenting***

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

7. Claim 18 is rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-3 of U.S. Patent No. 6,552,057.

Although the conflicting claims are not identical, they are not patentably distinct from

each other because the composition of U.S. '057 embraces the composition of the compound of the instant invention.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brenda Coleman whose telephone number is 571-272-0665. The examiner can normally be reached on 9:30-6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mukund Shah can be reached on 571-272-0674. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Brenda Coleman  
Primary Examiner Art Unit 1624  
September 10, 2004